

1 BRIAN M. BOYNTON
Acting Assistant Attorney General
2 GUSTAV W. EYLER
Director
3 Consumer Protection Branch
4 NATALIE N. SANDERS
ROGER J. GURAL
5 Trial Attorneys
Consumer Protection Branch
6 U.S. Department of Justice
450 5th Street, NW, Suite 6400-South
7 Washington, D.C. 20530
8 Telephone: (202) 598-2208
Facsimile: (202) 514-8742
9 E-mail: Natalie.N.Sanders@usdoj.gov
Attorneys for Plaintiff
10 UNITED STATES OF AMERICA
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12 UNITED STATES DISTRICT COURT
13 FOR THE CENTRAL DISTRICT OF CALIFORNIA
14 EASTERN DIVISION

15 UNITED STATES OF AMERICA,

16 Plaintiff,

17 v.

18 CALIFORNIA STEM CELL
19 TREATMENT CENTER, INC.,
20 *et al.*

21 Defendants.
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No. 5:18-CV-01005-JGB-KKx

**PLAINTIFF'S OBJECTIONS TO
DEFENDANTS' [PROPOSED] FINDINGS
OF FACT AND CONCLUSIONS OF LAW**

Trial: May 4 – 13, 2021

Honorable Jesus G. Bernal
United States District Judge

INTRODUCTION

Plaintiff United States of America hereby objects to Defendants' [Proposed] Findings of Fact and Conclusions of Law pursuant to Central District of California Local Rule 52-7. Certain of Defendants' proposed facts misrepresent the testimony of Government witnesses who, in fact, testified in direct opposition to Defendants' purported factual findings. Other proposed facts are not supported by any record evidence at all.

ARGUMENT

Defendants fail to adequately support the following proposed facts, in many cases citing to no evidence at all or to transcript excerpts that stand for the opposite. Specifically, the Government objects as follows:

- **No. 2:** Government expert witness Dr. Carolyn Yong did not testify that "SVF Cells are the naturally occurring part of the adipose tissue that does not contain the adipocytes (fat cells)." To the contrary, Dr. Yong testified that the select isolated cells that Defendants claim comprise SVF does not occur naturally in the body. The cells that comprise SVF are brought together only through elimination of the organized adipose tissue architecture and dismantling of organized multicellular structures. (5/7/21 PM at 6:8-8:3 (Yong)).
- **No. 3:** Dr. Yong did not testify that "[c]ells are the smallest and most basic functional structural units in the human body." Defendants cannot, and did not, cite any testimony from Dr. Yong on this point. Moreover, Dr. Yong also did not testify that "no person or device can remove *a stem cell* from adipose tissue without also removing *other tissue*." Defendants did not pose any such question to Dr. Yong, and the cited transcript excerpt does not support Defendants' contention that such removal is not possible.
- **No. 29:** Dr. Yong did not testify that the "SVF cells all demonstrated 'their multipotency by differentiating into cell types such as osteoblasts, adipocytes, bone, cartilage, and muscle cells.'" Rather Dr. Yong merely stated

1 on cross examination that Defendants read correctly that alleged result—
2 which is not even properly considered a conclusion—from a hearsay study.
3 Dr. Yong did not testify that the hearsay statement was accurate or that she
4 personally supported its assertion. (*5/7/21 PM Tr. 61:3-17 (Yong)*).

- 5 • **No. 30:** Dr. Yong did not testify that Liberase has no impact on the cells that
6 comprise SVF, including their viability or ability to differentiate, proliferate,
7 or function. Rather Dr. Yong testified extensively to the opposite—
8 confirming that Defendants’ enzyme mixture alters the physical and
9 biological characteristics of the SVF cells. (*5/7/21 PM Tr. 9:5-8, 72:17-25,*
10 *74:1-18, 74:20-23, 75:3-8, 75:16-20, 76:9-19, 78:24-25, 79:1-14 (Yong);*
11 *and 5/7/21 AM Tr. 80:5-12, 81:19-24, 82:3-10, 83:1-7, 84:11-21, 84:7-10,*
12 *84:22-85:2, 85:14-17, 85:18-24, 86:5-13, 86:18-87:10, 87:11-88:1-3*
13 *(Yong)*).
- 14 • **No. 35:** This Court instructed the parties to cite to the factual record for each
15 proposed finding of fact. (*5/13/21 PM Tr. 55:8-19*). Defendants have failed
16 to provide any factual citation for the proposition that “None of the articles
17 relied upon by the Government evaluates the effect of Liberase on . . . SVF
18 cells.” The lone citation to *5/7/21 PM Tr. 52:14-17 (Yong)* makes no
19 mention of SVF cells and cannot support this finding.
- 20 • **No. 36:** Dr. Yong did not testify that she “did not know which enzyme the
21 SVF Surgical Procedure utilized.” Rather, she testified that it “was not clear”
22 that Defendants’ CSN TMAX was, in fact, Liberase. She further explained
23 that her expert report had also cited to studies of enzymes other than Liberase
24 because “there are similarities between components of enzymes, you can
25 make reasonable arguments that phenomena can be applied to” cells. (*5/7/21*
26 *PM Tr. 72:16-73:3 (Yong)*).
- 27 • **No. 38:** Dr. Yong did not testify that changes in shape are temporary and/or
28 that they have no effect on the biological characteristics of cells. To the

1 contrary, she testified extensively about the impact of Defendants' processing
2 on the physical and biological characteristics of cells. (5/7/21 PM Tr. 9:5-8,
3 72:17-25, 74:1-18, 74:20-23, 75:3-8, 75:16-20, 76:9-19, 78:24-25, 79:1-14
4 (Yong); and 5/7/21 AM Tr. 80:5-12, 81:19-24, 82:3-10, 83:1-7, 84:11-21,
5 84:7-10, 84:22-85:2, 85:14-17, 85:18-24, 86:5-13, 86:18-87:10, 87:11-
6 88:1-3 (Yong)).

- 7 • **No. 74:** Conduct relating to the sending of adipose tissue to ACS and receipt
8 of the expanded SVF product was not outside the scope of FDA's 2017
9 investigation. Rather FDA investigator Michele Forster merely testified that
10 ACS was subject to a separate FDA investigation and was issued its own
11 FDA Form 483 listing objectionable conditions, and that she could not "speak
12 to any of the details" of that other aspect of FDA's investigation because she
13 did not personally conduct it. Ms. Forster also testified that she could not go
14 so far as to say that she did not find any violations by Defendants in
15 connection with the Expanded SVF product, as she "wasn't looking for it
16 [her]self. [But] there is . . . a responsibility of anyone who . . . ships
17 something in interstate commerce . . . to . . . follow the regulations. And so
18 even if it goes on to another firm where it then [becomes] adulterated, the
19 person who shipped it could be held responsible." (5/5/21 PM Tr. 35:10-
20 36:19 (Forster)).

- 21 • **No. 78:** Government witness Dr. Christopher Joneckis did not testify that
22 Defendants Berman and Lander "are permitted to perform the SVF treatments
23 on their patients subject to the conditions set forth in the IND approvals for
24 ACS." Rather Dr. Joneckis clearly stated that he had "no position" on
25 Defendants' use of such treatments, and that he was "not here to render an
26 opinion on that." (5/4/21 AM Tr. 74:21-75:10 (Joneckis)). Moreover, on
27 redirect, Dr. Joneckis confirmed that IND approval only permits the sponsor
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of the IND—not other third parties—to proceed with clinical studies. (5/4/21 AM Tr. 77:25-78:10 (*Joneckis*)).

- **No. 79:** This Court instructed the parties to cite to the factual record for each proposed finding of fact. (5/13/21 PM Tr. 55:8-19). This proposed fact is a bald unsupported assertion that lacks any support whatsoever, let alone adequate support.
- **No. 98:** Government witness Cynthia Jim did not testify that Defendants Berman and Lander “did not charge study participants for the SVF/ACAM2000 Surgical Procedure.” Rather investigator Jim stated *twice* that she could not remember whether Defendants charged their patients or not. 5/11/21 AM Tr. 85:9-14 (*Jim*). Moreover, the transcript excerpt that Defendants cited for their erroneous factual proposition—namely, 5/11/21 AM Tr. 85:15-18 (*Jim*)—does not address whether Defendants *charge* participants, but rather whether Defendants *paid* participants for their study involvement. Defendants’ cited evidence is, thus, wholly irrelevant to this fact and cannot possibly support it.

CONCLUSION

Plaintiff requests that the Court strike the proposed findings of fact that are not supported by the record and disregard such proposed findings when determining the conclusions of law.

Dated: June 15, 2021

Respectfully Submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

GUSTAV W. EYLER
Director

Consumer Protection Branch

/s/ Natalie N. Sanders

NATALIE N. SANDERS

ROGER J. GURAL

Consumer Protection Branch

U.S. Department of Justice

450 5th Street, NW, Suite 6400-South

Washington, D.C. 20530

Telephone: (202) 598-2208

Facsimile: (202) 514-8742

E-mail: Natalie.N.Sanders@usdoj.gov

Counsel for United States of America

Of Counsel:

DANIEL J. BERRY

Acting General Counsel

Department of Health and Human Services

PERHAM GORJI

Deputy Chief Counsel for Litigation

United States Food and Drug Administration

Office of the Chief Counsel

MICHAEL SHANE

MICHAEL HELBING

Associate Chief Counsel for Enforcement

United States Food and Drug Administration

Office of the Chief Counsel

White Oak 31, Room 4554

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Telephone: 301-796-8593

CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of June 2021, I electronically filed a true and correct copy of the foregoing PLAINTIFF'S OBJECTIONS TO DEFENDANTS' [PROPOSED] FINDINGS OF FACT AND CONCLUSIONS OF LAW through the Court's CM/ECF system, which will send a notice of electronic filing to the following counsel of record listed below:

Celeste M. Brecht
Ramanda R. Luper
JONES DAY

Matthew M. Gurvitz
Thomasina E. Poirot
Nicole N. King
Witt W. Chang
VENABLE LLP

/s/ Natalie N. Sanders
NATALIE N. SANDERS